

Missouri Department of Health & Senior Services

Health Update:

Enhancing Public Health Surveillance for Variant SARS-CoV-2 Viruses in Missouri

February 19, 2021

This document will be updated as new information becomes available. The current version can always be viewed at <http://www.health.mo.gov>.

The Missouri Department of Health & Senior Services (DHSS) is now using four types of documents to provide important information to medical and public health professionals, and to other interested persons:

Health Alerts convey information of the highest level of importance which warrants immediate action or attention from Missouri health providers, emergency responders, public health agencies or the public.

Health Advisories provide important information for a specific incident or situation, including that impacting neighboring states; may not require immediate action.

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Health Updates provide new or updated information on an incident or situation; can also provide information to update a previously sent Health Alert, Health Advisory, or Health Guidance; unlikely to require immediate action.

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Health Update
February 19, 2021

**FROM: RANDALL W. WILLIAMS, MD, FACOG
DIRECTOR**

SUBJECT: Enhancing Public Health Surveillance for Variant SARS-CoV-2 Viruses in Missouri

The Missouri Department of Health and Senior Services (DHSS) is issuing this health update to provide information regarding the public health surveillance for variant SARS-CoV-2 viruses in Missouri. The Missouri State Public Health Laboratory (MSPHL) participates in the national SARS-CoV-2 Sequencing for Public Health Emergency Response, Epidemiology and Surveillance (SPHERES) project and National SARS-CoV-2 Strain Surveillance (NS3) System led by the Centers for Disease Control and Prevention (CDC). DHSS has also established sentinel surveillance to detect variant SARS-CoV-2 viruses through the collaboration with five regionally selected healthcare system laboratories in Missouri. To further enhance the public health surveillance for variant SARS-CoV-2 viruses, Missouri healthcare providers can submit specimens from eligible individuals to the MSPHL, if approved as appropriate for variant surveillance. Guidance on the specific requirements, risk factors, process to request testing, and shipping of specimens is included in this Health Update.

Viruses constantly change through mutation, and new variants of a virus are expected to occur over time. Multiple variants of the virus that causes COVID-19 have been documented in the United States and globally during this pandemic. DHSS continues to participate in national efforts to enhance surveillance and respond to variant SARS-CoV-2 viruses.

Several new variants emerged in the fall of 2020, and most notable among them are: United Kingdom (UK) variant known as B.1.1.7; South African variant known as B.1.351; and the variant from Brazil, known as P.1. Each of these variants have been [reported in the United States](#); over 1,200 cases of B.1.1.7 infection have been reported from 42 states. Efforts are ongoing to learn more about these variants to better understand their transmissibility, their role in cases of reinfection, and the effectiveness of currently authorized vaccines against them. New information about the virologic, epidemiologic, and clinical characteristics of these variants is rapidly emerging.

Variant SARS-CoV-2 virus surveillance is intended for public health purposes, and obtained information is not intended for clinical decision making in order to augment acute clinical care. The testing of specimens and subsequent identification of variant viruses is a multi-step process, and final results will take at least one week after the specimen is received. It is also important to consider the testing capacity for variant viruses at the MSPHL is limited, and therefore, DHSS may not be able accommodate all requests for this public health surveillance effort. Medical providers can request the submission of specimens to the MSPHL for variant virus detection and identification. Requests will be considered when each of the stated requirements and at least one of the stated select criteria are met.

Requirements (*Each of these is required for approval for specimen submission*)

- All persons must have been diagnosed with COVID-19 by a positive viral diagnostic test, such as RT-PCR, other nucleic acid amplification test, or an antigen test.
- The RT-PCR Ct value is no more than 28. Not required if Ct value is not available, or can't be obtained
- Specimens must meet the required MSPHL submission criteria for COVID-19 testing available at <https://health.mo.gov/lab/ncov.php>, **and** must be received by the MSPHL within 72 hours of collection, **or** have been stored frozen and shipped frozen using dry ice.
- Prior approval from DHSS is obtained prior to specimen submission.

Select Criteria (*At least one of these is also required for approval for specimen submission*)

1. RT-PCR test results demonstrate the “S-gene dropout”. This criteria may change based on the frequency and distribution of the emerging virus variants.
2. Person developed onset of symptoms or tested positive (asymptomatic) within 14 days of returning from international travel.
3. Person developed onset of symptoms or tested positive (asymptomatic) within 14 days of exposure to a person meeting criteria #2 above.
4. Person is suspected of COVID-19 reinfection, including persons previously treated with monoclonal antibody, convalescent plasma, or antiviral drug Remdesivir.
5. Person is fully immunized with an approved COVID-19 vaccine per CDC guidelines and developed onset of symptoms greater than 14 days after receiving the final dose of vaccine.

Missouri healthcare providers can request the submission of specimens to the MSPHL for variant virus detection and identification by contacting DHSS Emergency Response Center at 1-800-392-0272, Monday through Friday, during the hours of 8:00 a.m. to 5:00 p.m. During the initial call, a DHSS staff member will ask questions to verify each of the “requirements” **and** at least one of the “select criteria” are met to approve specimen submission. Once approved, the specimen can be sent to the MSPHL for testing.

Submitting Specimens to the MSPHL: The submission of specimens to the MSPHL for testing and identification of variant SARS-CoV-2 viruses requires adhering to the following:

- Complete a MSPHL Test Request Form (TRF) for each specimen. The TRF is available online at <http://health.mo.gov/lab/>
- Must include that the specimen is submitted for variant virus surveillance on the TRF. It is also important to note on the TRF if vaccine breakthrough infection is suspected.
- Must include on the TRF what test was used to generate a positive result and the Ct values for each marker, as available.
- Specimen must contain at least 500 µL of viral transport media (VTM) or saline
- Store the specimens at -70°C pending shipment and ship on dry ice
- Affix shipping label to the outside of box and write: **SARS-CoV-2 Variant Surveillance** on box

SHIPMENT OF SPECIMENS

MSPHL Courier information is available at: <https://health.mo.gov/lab/courierservices.php> If you do not have access to the MSPHL Courier, please ship specimens by Fed Ex. Please do not ship samples for arrival at the MSPHL on weekends or holidays.

DO NOT SHIP CLINICAL SPECIMENS BY UPS.

For questions about packaging and shipping an approved specimen for variant virus surveillance to the MSPHL, please contact the MSPHL at 573-751-3334.

Variant testing of pre-approved specimens received at the MSPHL will include RT-PCR, viral sequencing, and sequencing analysis. Specimens with an RT-PCR Ct value at the MSPHL of 28 or greater will not be sequenced. Variant surveillance testing and identification is a multi-step process, and final results will take at least one week after specimen is received. Therefore, this surveillance effort is intended for public health purposes. It is critically important to continue to remind all persons diagnosed with COVID-19 of the importance of strictly adhering to the non-pharmaceutical interventions including, but not limited to, isolation and quarantine, social distancing, mask use, and good hand hygiene.

Missouri healthcare providers interested in submitting a specimen to the MSPHL for variant virus testing and identification or have questions regarding this health update should contact DHSS Emergency Response Center at 1-800-392-0272, Monday through Friday, during the hours of 8:00 a.m. to 5:00 p.m. For questions regarding the packaging and shipping an approved specimen for variant virus surveillance to the MSPHL, please contact the MSPHL at 573-751-3334.

Missouri Department of Health & Senior Services

Health Update:

Update: Indications for Monoclonal Antibodies in Management of COVID-19

September 15, 2021

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Health Update
September 15th, 2021

FROM: DONALD KAUEAUF, DHSS DIRECTOR

SUBJECT: Update: Indications for Monoclonal Antibodies in Management of COVID-19

As of July 30, 2021, FDA has authorized post-exposure prophylaxis (PEP) use of the COVID-19 monoclonal antibody therapeutic REGEN-COV (casirivimab and imdevimab). REGEN-COV is expected to be effective against circulating variants, including the Delta variant, and is authorized for outpatient treatment of patients with COVID-19. As of August 27, 2021, the FDA has reinstated bamlanivimab and etesevimab administered together for use only in states with low combined frequency of resistant variants. The bamlanivimab and etesevimab administered together are currently authorized for treatment in Missouri. Recent updates to the Emergency Use Authorizations (EUA) for COVID-19 monoclonal antibodies by the FDA also expanded the definition of “high-risk” outpatients who are eligible for treatment and provide greater latitude to healthcare providers to exercise their clinical judgment. Clinicians may now refer any adult or pediatric (age 12 years and older and ≥ 40 kg) outpatient for monoclonal antibody treatment if they have a medical condition or other factor, including race/ethnicity, that puts them at higher risk for progressing to severe COVID-19. Early testing, identification, and referral are vital for outpatient monoclonal antibody treatment.

Monoclonal antibodies (mAbs) directly neutralize the COVID-19 virus and are intended to prevent progression of disease. The mAbs are most effective when given early in infection. Evolving evidence demonstrates usefulness of mAb products in outpatient settings. Evidence from Eli Lilly mAb cocktail (bamlanivimab and etesevimab) trials showed potential to reduce hospitalization and death in infected people if given early in infection. Data from Regeneron mAb cocktail trial showed potential to decrease viral load and reduced medical visits in infected people if given early.

On August 27, 2021, the FDA reinstated the authorized use of [bamlanivimab and etesevimab administered together under Emergency Use Authorization \(EUA\) 094](#). Bamlanivimab and etesevimab are authorized for use only in states, territories, and U.S. jurisdictions in which the combined frequency of variants resistant to bamlanivimab and etesevimab administered together is less than or equal to 5%, as determined by FDA. The Centers for Disease Control and Prevention (CDC) determined that the [frequency of the SARS-CoV-2 B.1.617.2/Delta variant \(first identified in India\)](#) is increasing throughout the U.S. and has become the dominant variant in the US. Based on in vitro assays that are used to assess the susceptibility of viral variants to monoclonal antibodies, bamlanivimab and etesevimab, administered together, **are** expected to retain activity against the Delta variant (B.1.617.2). Based on these in vitro assays, bamlanivimab and etesevimab, administered together, **are not** expected to retain activity against the SARS-CoV-2 P.1/Gamma variant (first identified in Brazil), the B.1.351/Beta variant (first identified in South Africa), the AY.1 and AY.2 variants/Delta[+K417N] (commonly known as “Delta plus,” first identified in India) and the B.1.621 variant (first identified in Colombia). With the emergence of the B.1.617.2/Delta variant as the dominant variant in the U.S., the frequency of identified variants expected to be resistant to bamlanivimab and etesevimab administered together is steadily decreasing.

Based on the above, bamlanivimab and etesevimab administered together are currently authorized for use in Missouri (list of states, territories and U.S. jurisdictions in which bamlanivimab and etesevimab are and are not currently authorized is available on FDA’s website at:

<https://www.fda.gov/media/151719/download>).

ASPR has resumed distribution of bamlanivimab and etesevimab together and etesevimab alone (to pair with existing supply of bamlanivimab at a facility for use under the EUA).

Considering similar in vitro assay data currently available, REGEN-COV and sotrovimab are likely to retain activity against the P.1, B.1.351, AY.1 and AY.2, B.1.621, and B.1.617.2/Delta variants. As such, the use and distribution of REGEN-COV and sotrovimab are not impacted by the circulating variants based on information available at this time. All treatment delivery sites can continue ordering REGEN-COV from the authorized distributor by following the existing ordering and reporting procedures. All treatment sites may also find information on the [availability and ordering of sotrovimab](#) by visiting GlaxoSmithKline’s [website](#).

Current Indications for Monoclonal Therapy & Appropriate mAbs for Treatment

Post-Exposure Prophylaxis (PEP) in vulnerable persons (i.e. not fully vaccinated or immunocompromised) who are at high risk for progression to severe COVID-19

- *REGEN-COV* (casirivimab and imdevimab)

Active COVID-19 Infection in high risk individuals with mild to moderate symptoms

- *REGEN-COV* (casirivimab and imdevimab)
- *Bamlanivimab/Etesevimab*

- *Sotrovimab*

Eligibility for Post-Exposure Prophylaxis

REGEN-COV (casirivimab and imdevimab) is authorized for post-exposure prophylaxis of COVID-19 in individuals who are:

- Adult or pediatric (> 12 years of age and weighing at least 40kg) patient at high risk for progressing to severe disease or death
- Not fully vaccinated or who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications) AND
 - have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per CDC, OR
 - who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of COVID-19 in other individuals in the same institutional setting (for example, nursing homes, prisons)

Limitations of Authorized Use:

- PEP with REGEN-COV (casirivimab and imdevimab) is not a substitute for vaccination against COVID-19
- REGEN-COV (casirivimab and imdevimab) is not authorized for pre-exposure prophylaxis for prevention of COVID-19

Eligibility for Treatment of Mild-Moderate Covid-19 Infection in High Risk Individuals

Monoclonal antibodies granted EUA for mild to moderate COVID-19 cases early in infection, who are at high risk for progressing to severe COVID-19 and/or hospitalization with following criteria:

- Adult or pediatric (> 12 years of age and weighing at least 40kg) patient
- Confirmation via positive PCR or antigen test
- Treatment as soon as possible following positive viral test and within 10 days of symptom onset
- Patient symptomatic but not yet progressed to require hospitalization or oxygen therapy (or increase from baseline chronic oxygen therapy)

HIGH RISK FACTORS INCLUDE, BUT ARE NOT LIMITED TO:

- Older age (for example > 65 years of age)
- Obesity or being overweight (for example, adults with BMI > 25, or if age 12-17, have BMI > 85th percentile for their age and gender based on CDC growth charts)

- Pregnancy
- Chronic Kidney Disease
- Diabetes
- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease (including congenital heart disease) or hypertension
- Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis, and pulmonary hypertension)
- Sickle cell disease
- Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital abnormalities)
- Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19

Eligibility is not limited to the medical conditions and factors listed above. For additional information on medical conditions and factors associated with increased risk for progression to severe COVID-19, see the CDC website: <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>

How to Find Infusion Locations

Further information about monoclonal antibody infusions and where to access this treatment in Missouri is located at: <https://health.mo.gov/living/healthcondiseases/communicable/novel-coronavirus/monoclonal-antibody-treatment.php>

Specific information about each site, their referral procedures and location is available by clicking on the thumbtack for the site on the map.

Missouri healthcare providers and public health practitioners: Please contact your Local Public Health agency or the Missouri Department of Health and Senior Services' (DHSS') Bureau of Communicable Disease Control and Prevention at 573-751-6113 or 800-392-0272 (24/7) with questions regarding this Health Advisory.